BD Medical Systems
9450 South State Street
Sandy, Utah 84070
tel: 801.565.2300
fax: 801.565.2740
www.bd.com

APR 16 2002

K013621

BD

Indispensable to human health

Premarket Notification [510(k)] Summary

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood Manager, Regulatory Affairs
Telephone Number:	(801) 565-2504
FAX Number:	(801) 565-2749
Date Summary Prepared:	October 25, 2001
Trade Name:	BD Saf-T PRN Luer Activated Valve
Common Name:	Luer Activated Valve
Classification Name:	Accessory to an Intravascular Administration Set
Predicate Device:	Clave® Connector C-1000 ICU Medical Inc. K970855

Description of the BD Saf-T PRN Luer Activated Valve:

The BD Saf-T PRN Luer Activated Valve is a closed system that opens when a standard male luer taper is inserted and closes automatically when the male luer taper is disconnected. The BD Saf-T PRN valve permits injection, gravity flow or withdrawal of fluids. It is compatible with standard luer slip and luer lock adapters.

Intended Use of the BD Saf-T PRN Luer Activated Valve:

The BD Saf-T PRN Luer Activated Valve needleless connector is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids.

Technological Characteristics Comparison:

The BD Saf-T PRN Luer Activated Valve and the Clave Connector are both IV administration set accessories that provide needleless access. Both products are (1) activated by the insertion of a luer taper, (2) built with a polycarbonate body and silicone seal; (3) have the same indications for use, and (4) similar performance characteristics.

Nonclinical Tests Support Substantial Equivalence:

The following characteristics of the BD Saf-T PRN Luer Activated Valve and the Clave Connector C-1000 were shown to be substantially equivalent: actuation force, luer torque and pull forces, flow rate, back pressure, insertion force to access the device, leak testing, hemolysis, and microbial ingress.

Conclusions from Nonclinical Tests:

The BD Saf-T PRN Luer Activated Valve is substantially equivalent to the Clave® Connector C-1000 manufactured by ICU Medical.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Leslie Wood
Manager, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems, Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K013621
Trade/Device Name: BD SAF-T PRN Access Site, Model 385100
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 27, 2002
Received: February 28, 2002

Dear Ms. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Indications for Use:

21 CFR Part 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES
General Hospital and Personal Use Therapeutic Devices Sec. 880.5440:

An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter. An administration set may include the needle or catheter, tubing, flow regulator, drip chamber, infusion line filter, IV set stopcock, fluid delivery tubing, connectors between parts of the set, side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container.

The BD Saf-T PRN Luer Activated Valve needleless connector is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids.

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013621